

CLAIMS

1. An analytical test device incorporating a dry porous carrier to which a liquid sample suspected of containing an analyte can be applied indirectly, the device also incorporating a labelled specific binding reagent which is freely mobile in the porous carrier when in the moist state, and an unlabelled specific binding reagent which is permanently immobilised in a detection zone on the carrier material, the labelled and unlabelled specific binding reagents being capable of participating in either a sandwich reaction or a competition reaction in the presence of the analyte, in which prior to the application to the device of a liquid sample suspected of containing the analyte, the labelled specific binding reagent is retained in the dry state in a macroporous body through which the applied liquid sample must pass en route to the porous carrier material, the labelled specific binding reagent being freely soluble or dispersible in any liquid sample which enters the macroporous body.

2. An analytical test device according to claim 1, wherein the dry porous carrier material comprises a chromatographic strip.

3. An analytical test device according to claim 1 or claim 2, wherein the labelled specific binding reagent comprises a specific binding reagent attached to a particulate label.

4. An analytical test device according to claim 3, wherein the particulate label is latex.

5. An analytical test device according to claim 4, wherein the latex comprises particles having a maximum dimension of not greater than about 0.5 micron.

5 6. An analytical test device according to claim 4 or claim 5, wherein the latex is coloured.

7. An analytical test device according to claim 4 or claim 5, wherein the latex is fluorescent.

10 8. An analytical test device according to any one of claims 1 to 7, wherein the macroporous body comprises plastics material.

15 9. An analytical test device according to any one of claims 1 to 8, wherein the macroporous body has an average pore size of not less than 10 microns.

20 10. An analytical test device according to any one of claims 3 to 9, wherein the macroporous body has a pore size not less than 10 times greater than the maximum particle size of the particulate label.

25 11. An analytical test device according to any one of the preceding claims, wherein the porous carrier material is nitrocellulose.

30 12. An analytical test device according to claim 11, wherein the nitrocellulose has a pore size of greater than about 1 micron.

35 13. An analytical test device according to any one of the preceding claims, wherein the macroporous body is in direct moisture-conductiv contact with the porous carrier material, and the detection-zone in the porous carrier material is spaced away from the region of

contact of the porous carrier material with the macroporous body.

5 14. An analytical test device according to claim 13,
wherein the quantity of liquid sample required to
saturate the macroporous body is not less than the
quantity of liquid sample capable of being absorbed by
the mass of porous carrier material linking the
macroporous body and the detection zone.

10 15. An analytical test device according to any one of
the preceding claims, wherein the macroporous body and
porous carrier are contained within a casing or housing
constructed of moisture-impermeable material and having a
sample entry port communicating with the macroporous
body, the casing or housing also incorporating means to
enable the detection zone to be observable from outside
the casing or housing.

15 20 16. An analytical device according to any one of claims
1 to 14, wherein the porous carrier is linked via the
macro-porous body to a porous receiving member to which
the liquid sample can be applied and from which the
sample can permeate into the porous carrier.

25 30 35 17. An analytical device according to claim 16, wherein
the porous carrier and the macroporous body are contained
within a casing or housing constructed of
moisture-impermeable material and the porous receiving
member extends out of the casing or housing and can act
as a means for permitting a liquid sample to enter the
housing and reach the porous carrier, the casing or
housing being provided with means which enable the
detection zone of the porous carrier to be observable
from outside the casing or housing so that the result of
the assay can be observed.

18. An analytical device according to claim 17, wherein the casing or housing is provided with means which enable a further zone of the porous carrier to be observed from outside the housing and which further zone incorporates one or more control reagents which enable an indication to be given as to whether the assay procedure has been completed.

19. An analytical device according to either of claims 17 or 18, is provided with a removable cap or shroud which can protect the protruding porous receiving member during storage before use.

20. A pregnancy testing device comprising a hollow elongated casing containing a dry porous nitrocellulose carrier which communicates indirectly with the exterior of the casing via a bibulous urine receiving member which protrudes from the casing, the porous nitrocellulose carrier and the sample receiving member being linked via a macroporous body such that any sample reaching the porous carrier must first pass through the macroporous body, the sample receiving member and the macroporous body together acting as a reservoir from which urine is released into the porous carrier, the macroporous body containing a highly-specific anti-hCG antibody bearing a coloured direct label, the labelled antibody being freely mobile within the macroporous body and the porous carrier when in the moist state, and in a detection zone on the carrier spatially distant from the macroporous body a highly-specific unlabelled anti-hCG antibody which is permanently immobilised on the carrier material and is therefore not mobile in the moist state, the labelled and unlabelled antibodies having specificities for different hCG epitopes, the casing being constructed of opaque or translucent material incorporating at least one aperture through which the analytical result may be observed,

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together with a removable and replaceable cover for the protruding bibulous urine receiving member.

21. A fertile period prediction device, as claimed in
5 claim 21 except that the analyte is LH.

22. A device according to any one of the preceding
claims, wherein the liquid sample is aqueous.

10 23. A macroporous body containing in the dry state a
labelled specific binding reagent that is freely soluble
or dispersible in an aqueous sample that may be applied
to the macroporous body.

15 24. An analytical device incorporating a macroporous
body according to claim 23, together with a test strip or
the like into which liquid sample carrying dissolved or
dispersed labelled specific binding reagent can flow from
the macroporous body.

20 25. Use of a macroporous body according to claim 23 to
facilitate the uptake of a labelled specific binding
agent by a liquid sample before such a sample is analysed
on a test strip or the like.

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30 Add
B2

Add
C1

35 Add H3

Add E67

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